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**FINAL APPROVAL OF REVISED OU 2 FEASIBILITY  
STUDY/PROPOSED PLAN REPORTS**

01/20/95

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APPROVAL

DOE-FN



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

REGION 5  
77 WEST JACKSON BOULEVARD  
CHICAGO, IL 60604-3590

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JAN 20 1995

Mr. Jack R. Craig  
United States Department of Energy  
Feed Materials Production Center  
P.O. Box 398705  
Cincinnati, Ohio 45239-8705

HRE-8J

RE: Final Approval of Revised OU 2  
Feasibility Study/Proposed Plan  
Reports

Dear Mr. Craig:

The United States Environmental Protection Agency (U.S. EPA) has completed its review of the United States Department of Energy's (U.S. DOE) revised Operable Unit (OU) 2 Feasibility Study (FS)/Proposed Plan (PP) Reports. There have been several meetings, teleconferences and discussions between representatives of U.S. DOE, U.S. EPA and the Ohio Environmental Protection Agency concerning these documents. All outstanding issues have been resolved to U.S. EPA's satisfaction, except one issue concerning the use of non-parametric statistical methodologies in the risk assessment calculations.

It remains U.S. EPA's position that U.S. DOE has incorrectly used these methodologies in the OU 2 documents. However, given the OU 2 proposed remedy, exhumation of the waste materials and disposal in an on-site disposal cell, the risk assessment methodology used by U.S. DOE will not significantly impact the risk assessment or proposed remedial decision.

Although this issue does not warrant further resource expenditures in regards to OU 2, this above risk assessment issue may significantly impact the OU 5 FS report. U.S. EPA has provided input to U.S. DOE on how to correctly proceed using the statistical procedure and has attached further comments to be addressed in future documents. The OU 5 FS report must correctly utilize this statistical procedure before the report can be approved.

Therefore, U.S. EPA hereby approves the OU 2 FS and PP reports. A final copy of the documents should be submitted to U.S. EPA within thirty (30) days receipt of this letter. U.S. EPA also recommends a meeting to discuss the statistical procedures used in the OU 5 FS report.

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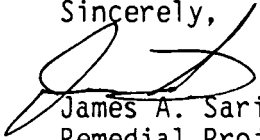


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Please contact me at (312) 886-0992 if you have any questions.

Sincerely,



James A. Saric  
Remedial Project Manager  
Technical Enforcement Section #1  
RCRA Enforcement Branch

Enclosure

cc: Tom Schneider, OEPA-SWDO  
Jack Baublitz, U.S. DOE-HDQ  
Don Ofte, FERMCO  
Jim Thiesing, FERMCO  
Paul Clay, FERMCO

1/25/95

Note to: Pat Van Leewuen, Region 5  
From: Paul White, EAG *PW*  
Subject: Fernald concentration term estimates

The following note summarizes (with a bit of elaboration) some points we discussed in our phone call today:

(1) Within an exposure area, EPA's principal concern rests with the mean concentration of contaminant, and the uncertainty in the estimate of the mean. In the absence of highly detailed site use information, the area mean concentration is judged to provide the best indicator of the integrated concentration that a user of that site area would contact over time.

(2) Where data show that neither normal or lognormal models were consistent with the contaminant distribution within an exposure area, EPA and DOE had agreed to use a 95th percentile of the concentration distribution as a surrogate for a mean concentration value. This approach rests on the assessors' judgements that the true mean concentration is not likely to exceed the measured 95th percentile concentration.

(3) The approach outlined in (2) is motivated by the need to have a practical method of dealing with relatively data rich situations, where the concentration data are not consistent with assumptions of a parametric statistical analysis, and where the 95th percentile of the distribution can be appropriately estimated. In my judgement such an approach is not appropriate for some of the Fernald data sets which had a large fraction of samples with concentrations below reported limits (I will call these "non-detects" for simplicity) If, there are a bunch of "non-detects" with reporting limits higher than the levels for the samples with measured concentrations, then the 95th percentile of the data can not be appropriately estimated using non-parametric techniques. In this case the approach in (2) is no longer supportable as a reasonable means to estimate the concentration term. This is a generic concern, and holds for any of the alternate approaches that may have been taken to ordering concentration values and non-detects for counting in such a data set.

(4) I suggest the following approach be considered when there are many "non-detects" with reporting limits above the levels for samples with measured concentrations: Simply average together all the exposure area data including the measured values and the reporting limits for the "non-detects". The value obtained from this calculation is interpreted as an upper bound on the concentration term. Note that this approach uses the reporting limit itself and not 1/2 or another fraction of this value. This is because the attempt here is to directly calculate a upper bound on the mean concentration, not to manipulate the reporting limits to support a best guess about the non-reported concentrations. Note that reporting limits are used here as they appear to be the only values available that provide upper bounds

on concentrations for samples with no measured concentration.

Note that, more precisely, we are obtaining an upper bound on the mean concentration for the collected set of samples. In the rather problematic situation we are discussing, the bound on the sample mean would be higher than the measured concentration values. An additional exercise of the assessors judgement would be needed to support a presumption that the true area mean was unlikely to be higher than this bound on the sample mean. This interpretation would presume that the sample data were representative of the area being assessed (or at least not biased towards an underestimate the concentration). There should not be reason to suspect that more highly contaminated areas were missed in the sampling. In my judgement, I would not pursue this approach if less than ten sample points were available. In that case, I would recommend additional data collection.

(5) It is my understanding that the peculiarity of this situation, where there are large numbers of high reporting limits for "non-detects", stems from contractual considerations about the required performance for labs rather than an accurate, scientific, expression of the quantity of a compound would have been seen (and recorded) in individual samples. This situation unnecessarily complicates the challenge of analyzing site data and can cause the concentration term estimates to be unnecessarily uncertain. I would strongly urge that our Agencies take steps to obtain, report, and use limits that reflect the lowest concentrations that would have been measured (and recorded) if they were indeed present.

(6) It may be possible to reexamine some of the Fernald data to determine whether lower reporting limits levels can be assigned for individual samples than the contract required levels. If some clean-up actions will be triggered by the analyses of data sets having high reporting limits, then a reexamination of the laboratory data from this perspective would be particularly relevant.

I have also discussed many of these issues with Mat Nataw, who is providing statistical support for DOE in the Fernald assessment and appreciate the insights that he has offered.